

Have you been  
diagnosed with

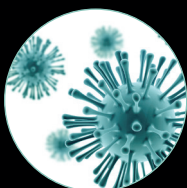
# PERIODONTAL DISEASE?

Talk to your Dental Healthcare Professional about PerioChip (chlorhexidine gluconate) 2.5 mg.

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# What you need to know about Periodontal Disease

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Periodontal disease (also called gum disease) is a chronic, bacterial infection of the gums that can **destroy the tissue and bone supporting the teeth.**<sup>1</sup>



Without treatment, periodontal (gum) disease can get worse, and may **cause tooth loss.**<sup>1</sup>



The most important risk factor for periodontal (gum) disease is smoking.<sup>1</sup>

**Some additional risk factors include poor oral health habits, diabetes, heredity, older age, poor nutrition, and substance abuse.**<sup>4</sup>



The Center for Disease Control states that as many as **64 million American adults** have periodontal disease.<sup>2</sup>

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## What are the symptoms of Periodontal (Gum) Disease?

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Some of the first signs of gum disease are **sore, bleeding gums and bad breath.**<sup>5</sup>



Periodontal disease can also happen and get worse without causing pain, so **many people who have it don't even realize it.**



As disease progresses, symptoms can include **gums that recede from your teeth**, and make them look longer, **new spaces between your teeth**, **loose teeth**, and a **change in the way your teeth fit together when you bite.**

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## How is Periodontal Disease diagnosed?

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### At your visit, your dentist or hygienist will:

- > Ask about your medical history and behaviors like smoking that may contribute to periodontal (gum) disease.<sup>5</sup>
- > Examine your gums for signs of bleeding, swelling, infection and inflammation.<sup>5</sup>
- > Use a tiny dental device called a “probe” which acts like a tiny ruler to measure pockets surrounding the teeth. In a healthy mouth, these pockets are usually between 1 mm and 3 mm deep.<sup>5</sup>



## Scaling and Root Planing

Moderate Periodontal disease is usually treated with a non-surgical treatment called scaling and root planing (SRP), in which the Dental Healthcare Professional cleans below the gum line of the tooth to remove the bacterial infection.<sup>5</sup> However, your Dental Healthcare Professional may determine that SRP may not be enough to treat the bacteria.

**SRP combined with adjunctive therapy has proven to be an effective treatment for adult periodontal disease.**



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## PerioChip®: An Adjunct to Scaling and Root Planing

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- > **PerioChip®** (Chlorhexadine Gluconate) 2.5 mg is a unique, non-antibiotic, antiseptic biodegradable chip active against periodontal bacteria after SRP. The relationship of the microbial findings to clinical outcome has not been established.
- > **PerioChip®** is indicated as an adjunct to SRP procedures for reduction of pocket depth (PD) in patients with adult periodontitis (a moderate form of gum disease) with a PD  $\geq$  to 5 mm. **PerioChip®** may be used as a part of a periodontal maintenance program, which includes good oral hygiene and SRP.
- > **PerioChip®** should not be used in any patient who has a known sensitivity to chlorhexidine. Patients should report adverse reactions, including allergic reactions, to their Dental Healthcare Professional.
- > **PerioChip®** has been shown in a test tube (*"in vitro"*) to fight bacteria for 7-10 days. **PerioChip®** is effective against a broad range of microbes.
- > **PerioChip®** can kill bacteria that SRP leaves behind in gum pockets  $> 5$  mm.

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## PerioChip®

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**PerioChip®** is a small thin wafer that your Dental Healthcare Professional inserts under the gums into the periodontal pocket with probing PD of  $\geq 5$  mm after SRP.

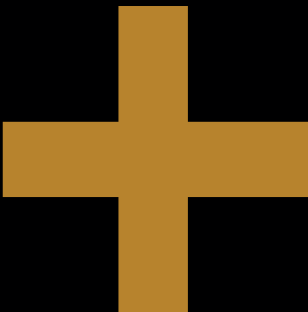
Treatment may be recommended by your Dental Healthcare Professional to be administrated once **every 3 months** in pockets with PD remaining 5 mm or greater.



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### Is PerioChip® treatment painful?

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Typically, placement of **PerioChip®** is quick and generally painless. You may have some mild-to-moderate sensitivity in the first week after the chip is placed. This is normal. However, patients should notify the dentist promptly if pain, swelling, or other problems occur.

If you have extra-sensitive gums, your Dental Healthcare Professional can apply a topical anesthetic before placing **PerioChip®**.

You won't need to go back to the dentist to have **PerioChip®** removed, since it biodegrades completely over the course of therapy.

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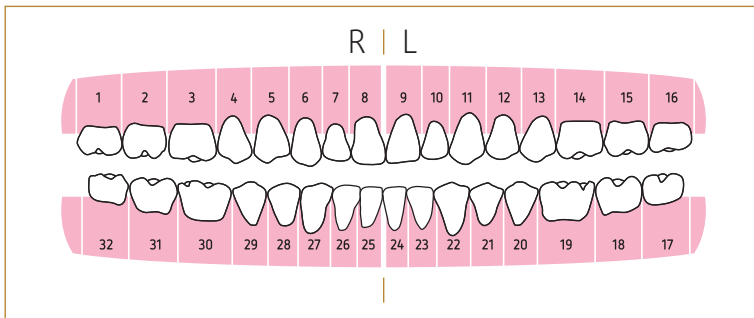
## What's the follow-up care like?

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- > Patients shouldn't floss at the site of **PerioChip®** insertion for **10 days** after it's placed, **since flossing might dislodge the chip**. If the chip does dislodge, patients should let their dentist know right away. All other oral hygiene may be continued as usual.
- > A Dental Healthcare Professional may place **PerioChip® every 3 months** in periodontal pockets with PD remaining 5 mm or more. **PerioChip®** may be used as a part of a periodontal maintenance program, which includes good oral hygiene and SRP (scaling and root planing).

**PerioChip® can be used when other adjunctive treatments have failed.**

- > This chart indicates Pocket Depths (PD) on Your teeth that require treatment:



### Your Next Dental Appointment:

time \_\_\_\_\_

date \_\_\_\_\_



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# PerioChip® Important Safety Information

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## > Contraindications

PerioChip® [chlorhexidine gluconate] 2.5 mg should not be used in a patient who has a known sensitivity to chlorhexidine.

## > Warnings

Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine.

Patients should be advised to report any signs of local adverse reactions to their dentists. Patients who develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or diarrhea, should seek medical attention immediately.

## > Precautions

The use of PerioChip® in an actually abscessed periodontal pocket has not been studied and therefore is not recommended. Although rare, infectious events including abscesses and cellulitis, which have been reported after scaling and root planing (SRP) alone, have also been reported with the adjunctive placement of the PerioChip® post SRP. Management of patients with periodontal disease should include consideration of potential contributing medical disorders, such as cancer, diabetes, and immunocompromised status.

### • Information for Patients

Patients should be advised that, although some mild to moderate sensitivity is normal during the first week after placement of PerioChip®, they should notify the dentist promptly if pain, swelling, or other problems occur.

Most oral sensitivity or pain occurred within the first week of initial chip placement following SRP alone, was mild-to-moderate in nature, and spontaneously resolved within days. These reactions were observed less frequently with subsequent chip placement at 3 and 6 months.

Patients should avoid dental floss at the site of the PerioChip® insertion for 10 days after placement, because flossing might dislodge the chip. All other oral hygiene may be continued as usual. No restrictions regarding dietary habits are needed. Dislodging of the PerioChip® is uncommon; however, patients should be instructed to notify the dentist promptly if the PerioChip® dislodges.

In the unlikely event of PerioChip® dislodgement (in the two pivotal clinical trials, only 8 chips were

reported lost), several actions are recommended, depending on the day of PerioChip® loss.

If dislodgement occurs 7 days or more after placement, the dentist should consider the subject to have received a full course of treatment. If dislodgement occurs within 48 hours after placement, a new PerioChip® should be inserted. If dislodgement occurs more than 48 hours after placement, the dentist should not replace the PerioChip®, but re-evaluate the patient at 3 months and insert a new PerioChip® if the pocket depth has not been reduced to less than 5 mm.

### • Pregnancy

PerioChip® should be used in a pregnant woman only if clearly needed.

### • Pediatric Use

The safety and effectiveness of PerioChip® in pediatric patients have not been established.

### • Geriatric Use

Although subjects aged 65 years and over were included in clinical studies of PerioChip®, there were not sufficient numbers of these subjects to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Overall differences in safety or effectiveness have not been identified between the elderly and younger patients.

## > Adverse Reactions

The most frequently observed adverse events in the two pivotal clinical trials, that compared the effects of SRP, and SRP followed by PerioChip® treatment, were toothache, upper respiratory tract infection and headache. Toothache was the only adverse reaction that was significantly higher ( $p=0.042$ ) in the PerioChip® group (50.7%) when compared to placebo (41.4%).

The risk information provided here is not comprehensive. To learn more, talk to your Dental Healthcare Professional about PerioChip®. The FDA-approved product labeling can be found at [www.periochip.com](http://www.periochip.com).

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call

1-800-FDA-1088

# PerioChip<sup>®</sup>

[chlorhexidine gluconate] 2.5mg

**Dexcel<sup>®</sup>**  
p h a r m a

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**References:** 1. Gum (Periodontal) Diseases. National Institute of Dental and Craniofacial Research website. <http://www.nidcr.nih.gov/oralhealth/Topics/GumDiseases/>. Accessed August 1, 2014. 2. <http://www.perio.org/consumer/cdc-study.htm#OverlayWrapper/0/>. Accessed August 4, 2014. 3. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3100856/>. Accessed August 4, 2014. 4. <http://www.mayoclinic.org/diseases-conditions/periodontitis/basics/risk-factors/con-20021679>. Accessed August 4, 2014. 5. Gum (Periodontal) Diseases: Causes, Symptoms, and Treatment. National Institute of Dental and Craniofacial Research website. <http://www.nidcr.nih.gov/oralhealth/Topics/GumDiseases/PeriodontalGumDisease.htm>. Accessed August 1, 2014.

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